REMARKS

Reconsideration of the rejections set forth in the Office Action dated February 13, 2007, is respectfully requested. Claims 46-51 are currently pending. Claims 46, 47, 50 and 51 have been amended. No new claims or matter has been added. No claims have been canceled by way of the present amendment.

Claims 46-51 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner has alleged the specification fails to explicitly disclose the use of MRI and ultrasound to detect the marker and predetermined time periods.

Applicants respectfully assert that claims 46-51 do comply with the enablement requirement of § 112, first paragraph. "The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). According to MPEP § 2164.01, "[a] patent need not teach, and preferably omits, what is well known in the art."

With respect to disclosure of "the use of MRI and ultrasound to detect the marker," Applicants respectfully assert that on page 2 of the present application Serial Number 08/217,246 is incorporated by reference and thus forms part of the specification for the present application. In the '246 application, now U.S. Patent No. 5,526,822, the use of MRI and ultrasound imaging systems are disclosed. The '822 patent includes the following statement, "[w]ith the advent of medical imaging equipment (x-rays and fluoroscopy, computed tomography, ultrasound, nuclear medicine, and magnetic resonance imaging) it became possible to identify small abnormalities even deep within the body." Col. 1, lines 46-50, of the '822 patent. All of these imaging systems were well known at the time of Applicants' invention and form part of Applicants' specification.

Further, the '822 patent discloses the use of these imaging systems with temporary markers. Col. 2, lines 6-39, of the '822 patent states:

> The open method is illustrated in FIGS. 1A through 1E. FIG. 1A depicts an accurately localized lesion. A lesion 5 is located per one of the aforementioned visualization means. The breast 1 is pierced with a localization wire 3 with the intention of positioning the large diameter section of the wire through the center of the lesion to act as a temporary marker. In a subsequent procedure, tissue is removed around the area marked by the localization wire. The tissue is then prepared and sectioned for evaluation. Open surgical breast biopsies have many drawbacks. They can be disfiguring, expensive (in terms of direct costs to the patient and indirect costs to society from the patient being away from work), and are imperfect (the error rate for surgical biopsy has been reported to be from 2% to 22%). FIG. 1B illustrates a localization wire 3 incorrectly placed by a radiologist. FIG. 1C illustrates a properly placed localization wire 3 but poor tissue selection 7 by the surgeon in which the lesion 5 was not harvested. FIGS. 1D and 1E illustrate a properly harvested lesion 9 with the wrong section prepared for analysis. As shown, the lesion 5 is included in the harvested tissue sample 9. However, in sectioning the tissue sample 9 along A--A and B--B for examination, the lesion 5 was missed. Any of these errors will lead to an incorrect diagnosis of the lesion. Open surgical biopsies also carry a small mortality risk (the risk of anesthesia) and a moderate morbidity rate (including bleeding, infection, and fracture or migration of the localizing wire). In cases where multiple lesions are present in the breast, a surgeon is reluctant to biopsy each lesion due to the large tissue mass that must be extracted with each lesion. The most convenient lesion is taken which results in an incomplete diagnosis. Finally, surgical breast biopsies are extremely common. In the United States, alone, it is estimated that open, surgical breast biopsies are performed on over 500,000 women annually. A less invasive alternative has long been sought.

As stated previously, Applicants describe the marker element as being "preferably comprised of a ... substantially radiopaque material." See Page 9, lines 16-17, of the present application. Applicants respectfully submit radiopaque materials have the ability to be remotely imaged using x-rays and fluoroscopy, computed tomography, ultrasound, nuclear medicine, and magnetic resonance imaging, which is well documented in the patent literature (see USPN 5,344,640). Additionally, Applicants describe known imaging systems as including x-ray, ultrasound, or magnetic resonance imaging (MRI). See Page 3, lines 12-16, of the present application. Applicants further state that "[t]he markers should be easy to deploy and easily detected using state of the art imaging techniques". Page 6, lines 6-7, of the present application. All of the above were state of the art techniques at the time of filing of this application and as such are all either positively or inherently

disclosed. Radiodense materials are also described that are "highly visible by mammographic imaging. ... During subsequent imaging procedures, they would function to denote the location of the previous biopsy for reference purposes". Page 22, line 23 - Page 23, line 1, of the present application. Based on the disclosure of the present application, one skilled in the art would be able to make and use a marker that was detectable via any of x-rays and fluoroscopy, computed tomography, ultrasound, nuclear medicine, and magnetic resonance imaging. Therefore, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims.

Use of the language "predetermined time periods for which the marker remains at the site" has also been rejected under 35 U.S.C. § 112. The language used in independent claims 46 and 51 has been amended and is now believed to be supported by Applicants' specification. Applicants respectfully assert a marker made of biodegradable material would remain at the cavity site for a first period of time until it degrades. Therefore, one skilled in the art would be able to make and use a detectable mass that remains at the cavity site for a first period of time based on the description of biodegradable polymers. Although not necessary to support Applicants' claims, biodegradable polymers which degrade in predetermined periods were well known in the art at the time of Applicants' filing (see USPN 4,351,337).

Claims 46-51 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Nash et al. (USP 5,411,520). This rejection is respectfully traversed in view of the preceding amendments and the remarks which follow.

Claim 46 now defines an intracorporeal marker for marking a cavity site within the body of a mammalian patient from which a tissue sample has been removed during a biopsy. The intracorporeal marker includes a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site created when the tissue has been removed. The mass of material remains detectable at the cavity site for a first period of time after its introduction into the cavity site and does not interfere with imaging of tissue adjacent the cavity site after the first period of time.

It is highly desirable to mark the location or margins of a cavity site created as a result of a biopsy for ensuring the entire lesion is excised or for future identification of the cavity site. Nash is not concerned with marking a cavity site and, consequently does not teach or suggest a marker for marking a cavity site. Claim 46 specifies that the marker is "for marking a cavity site within the body of a mammalian patient from which a tissue has been removed during a biopsy." Similarly, claim 51 specifies that the marker is "for marking a cavity site from which a tissue sample has been removed during a biopsy." Applicants explicitly claim and, therefore, a prior art reference is required to disclose, that the cavity site is created by the removal of tissue during a biopsy.

In contrast, Nash describes a method for sealing a percutaneous puncture in a blood vessel. See Abstract; See also Col. 5, lines 59-63, of Nash. A punctured blood vessel is not a cavity site created by the removal of tissue during a biopsy as required by independent claims 46 and 51. A puncture occurs by cutting or piercing tissue, that is, the tissue is merely displaced and not removed, and the spacer 36 is not a marker for a cavity site of a biopsy. As seen in Figs. 21 and 27 of Nash, the implant of Nash is inserted into a puncture tract that extends through the vessel wall. Nash is not concerned with marking a cavity site because the puncture tract is not a cavity formed by the removal of a portion of tissue during a biopsy.

More importantly, the device of Nash is not even a marker, it is a spacer 36 used in closing a hole in a blood vessel. Although a portion of the spacer 36 may include a radiopaque additive (in particular, the spacer 36), there is vast difference between a marker designed to identify a biopsy site and a spacer 36 used in closing a hole.

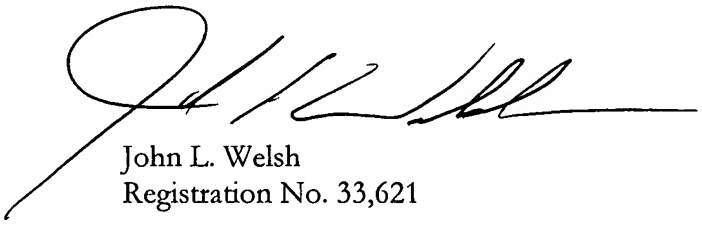
In fact, Nash's implant was specifically designed for use in a puncture tract that extends all the way through the vessel wall, which is not a cavity in the vessel wall formed by removal of tissue during a biopsy, and not as a marker.

With the foregoing in mind, Applicants respectfully assert the cited reference does not teach or suggest all of the limitations of the pending claims.

For all the reasons stated above, Applicants respectfully request withdrawal of the rejections of claims 46 and 51, and reconsideration of the claims as amended. Claims 47-50 depend from claims 46 and are, therefore, patentably distinct for at least the reasons as stated above.

It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact Applicants' representative at the below number.

Respectfully submitted,



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